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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/782,728

02/18/2004

Peter C. Brooks

31747-705.201

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06/09/2008

WILSON SONSINI GOODRICH & ROSATI

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

06/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/782,728 | Applicant(s) BROOKS ET AL. | |
| | Examiner ROY TELLER | Art Unit 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 6-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 6-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/14/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the remarks, filed 2/25/08.

Claims 2 and 6-12 are under examination.

Information Disclosure Statement

The information disclosure statement, received 4/14/08, is acknowledged. A signed copy is enclosed hereto.

Response to Amendments/ Arguments

Applicant's arguments and amendments filed 2/25/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claim Rejections - 35 USC § 102/103

Claims 2 and 6-12 are/stand rejected under 35 USC 102/103 for the reasons of record which are restated below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 6-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brooks (US 7,122,635).

The claims are drawn to a a denatured collagen type-IV selective peptide antagonist wherein the binding affinity of the denatured collagen type-IV selective antagonist to denatured type-IV collagen is substantially greater than the binding affinity of said antagonist to native collagen type-IV.

Brooks discloses antagonists of the invention bind to a denatured collagen but bind with substantially reduced affinity to the native form of the collagen. This is taken to mean that Brooks antagonist binds to denatured collagen with a greater affinity than the binding affinity of that of native collagen. A "substantially reduced affinity" is an affinity of about 3-fold lower than that for the denatured collagen, more preferably about 5-fold lower, and even more preferably about 10-fold lower, and even more preferably greater than 10-fold lower. Likewise, "substantially less" indicates a difference of at least about a 3 fold difference when referring to relative affinities. In another embodiment, an antagonist binds to denatured collagen type-IV but binds with substantially reduced affinity to native collagen type-IV. See, i.e., for example, column 3, lines 1-17. It is acknowledged that the '635 patent does not disclose instant SEQ ID NO: 1, but given that the '635 patent discloses the same activity of antagonists that bind to the

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denatured collagen type-IV antagonist and given that an antagonist also can be a polypeptide or peptide with specificity for denatured collagen, but not for a native form of the collagen, it would be inherent that the activity should correlate to the structure of the denatured collagen type-IV antagonist. It should also be noted the cited reference discloses that the denatured collagen IV (to which the peptide antagonist binds) is preferably obtained via the same steps as instant disclosed (see, e.g., Brooks et al. - col 9, line 56 - col 10, line 34; and the instant specification - pages 13-14). Thus, the denatured collagen IV peptide antagonist instantly claimed appears to be identical to (thus, anticipated by) the denatured collagen IV peptide antagonist disclosed by the cited reference.

In the alternative, even if the claimed denatured collagen type-IV selective peptide antagonist is not identical to the referenced denatured collagen type-IV selective peptide antagonist with regard to some characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced denatured collagen type-IV selective peptide antagonist is likely to inherently possess the same characteristics of the claimed denatured collagen type-IV selective peptide antagonist, particularly in view of the similar characteristics which they have been shown to share. Thus the claimed denatured collagen type-IV selective peptide antagonist would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please also note that “the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process.” In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Applicant’s arguments were carefully considered but were not found persuasive. Applicant contends that the official action failed to meet the burden of proof required for a rejection based on inherency. Further, applicant contends that the office action fails to set for a *prima facie* case of obviousness against the instant claims based on the cited prior art. However, the examiner contends that with respect to Applicant's argument that the reference does not expressly teach that their denatured collagen type-IV antagonist comprises the instantly claimed sequence. Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants’ denatured collagen type IV antagonist differs and, if so, to what extent, from that disclosed by the cited reference (including with respect to inherently comprising the instantly claimed sequence). Therefore, with the

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showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants. Further, the examiner contends that hindsight reasoning was not relied upon for an inherency argument - it is relying on the fact that the reference product and the claimed product appear to be the same or at least obvious within the meaning of USC 103 based upon similarities they have been shown to share- as discussed fully within the USC 102/103 rejection of record. Therefore, without clear and convincing objective evidence to the contrary the rejection is maintained.

Conclusion

All claims are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
6/5/08

/Christopher R. Tate/
Primary Examiner, Art Unit 1655